

# Leading Addiction Focused Company Adial Pharmaceuticals Comments on Lancet Article Reporting Alcohol is the Number One Cause of Death Globally Among Ages 15 to 49

*Adial seeks to rapidly advance its drug AD04 through Phase 3 trials to become an important tool in combating alcohol use disorder*

CHARLOTTESVILLE, Va., Aug. 27, 2018 — **Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW)**, a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today commented on the [article](#) published on Thursday, August 23<sup>rd</sup>, in [The Lancet](#), which reports that alcohol is the number one cause of death globally among both men and women ages 15 to 49 years. The Lancet is one of the world's leading medical journals with open access funded by the Bill & Melinda Gates Foundation.

Data was derived from 694 sources of individual and population-level alcohol consumption and 592 studies on the risk of alcohol use, and the study produced estimates of drinking rates, alcohol attributable deaths, and the effect on disability-adjusted life-years (DALYs).

"This milestone Lancet article sheds bright light on the dangers of alcohol and the massive global mortality it inflicts. Alcohol use disorder (AUD) does not discriminate-killing our children, our parents, our soldiers, our teachers, and even our doctors. This disease destroys families and fractures communities," stated William Stilley, CEO of Adial Pharmaceuticals. "It's been almost 100 years since passage of the Volstead Act, a constitutional amendment prohibiting alcohol that was eventually repealed, and the rate of AUD continues to rise. Moreover, after all this time, there are still very limited medical options for those with this disease. Rather than demonizing those with AUD, we need to address the biological and physiological causes in order to find effective treatments. At Adial, we are aggressively working to commence our phase 3 trial for AD04, which is uniquely designed to treat AUD by reducing drinking while avoiding the side effects of other products on the market. Ultimately, we believe AD04 will become an important tool in the war against AUD, and possibly other addictions."

According to the National Institute of Alcohol Abuse and Alcoholism (the "NIAAA") and the Journal of the American Medical Association ("JAMA"), in the United States alone, approximately 35 million people each year have AUD, resulting in significant health, social and financial costs with excessive alcohol use being the fourth leading cause of preventable death and is responsible for 31% of driving fatalities in the United States (NIAAA Alcohol Facts & Statistics). AUD contributes to over 200 different diseases and 10% of children live with a person that has an alcohol problem. According to the American Society of Clinical Oncologists, 5-6% of new cancers and cancer deaths globally are directly attributable to alcohol. The Centers for Disease Control (the "CDC") has reported that AUD costs the U.S. economy about \$250 billion annually, with heavy drinking accounting for greater than 75% of the social and health related costs. Despite this, according to the article in the JAMA 2015 publication, only 7.7% of patients (i.e., approximately 2.7 million people) with AUD are estimated to have been treated in any way and only 3.6% by a physician (i.e., approximately 1.3 million people). In addition, according to the NIAAA, the problem in the United States appears to be growing with almost a 50% increase in AUD prevalence between 2002 and 2013.

## About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of treatments for addictions. The Company's lead investigational new drug product, AD04, is a genetically targeted therapeutic agent for the treatment of alcohol use disorder ("AUD"). A Phase 2b clinical trial of AD04 for the treatment of AUD showed promising results in reducing frequency of drinking, quantity of drinking and heavy drinking (all with statistical significance), and no overt safety concerns (there were no statistically significant serious adverse events reported). The Company plans to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes, which are to be identified using the Company's proprietary companion diagnostic genetic test. AD04 is also

believed to have the potential to treat other addictive disorders such as opioid use disorder, gambling, and obesity.

## **Forward Looking Statements**

This communication contains certain “forward-looking statements” within the meaning of the U.S. federal securities laws. Such statements are based upon various facts and derived utilizing numerous important assumptions and are subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Statements preceded by, followed by or that otherwise include the words “believes,” “expects,” “anticipates,” “intends,” “projects,” “estimates,” “plans” and similar expressions or future or conditional verbs such as “will,” “should,” “would,” “may” and “could” are generally forward-looking in nature and not historical facts, although not all forward-looking statements include the foregoing. These statements are based upon current beliefs, expectations and assumptions and include statements regarding the belief that AD04 will become an important tool in the war against AUD, and possibly other addictions, the planned Phase 3 clinical trial and the use of AD04 for the potential treatment of AUD in subjects with certain target genotypes. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, the ability of AD04 therapy to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, our ability to use the previously manufactured clinical trial material to advancing our Phase 3 clinical trial of AD04 and our plan to become a leading player in the war on addiction, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to our ability to promote or commercialize our product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products, our ability to maintain our license agreements, the continued maintenance and growth of our patent estate, our ability to establish and maintain collaborations, its ability to obtain or maintain the capital or grants necessary to fund its research and development activities, and our ability to retain our key employees or maintain our Nasdaq listing. These risks should not be construed as exhaustive and should be read together with the other cautionary statement included in our registration statement on Form S-1 that we have filed with the SEC and the final prospectus. Any forward-looking statement speaks only as of the date on which it was initially made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise, unless required by law.

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